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(71) Applicant (*for all designated States except US*): BAUSCH & LOMB INCORPORATED [US/US]; One Bausch & Lomb Place, Rochester, NY 14604-2701 (US).

(72) Inventors; and

(75) Inventors/Applicants (*for US only*): JIN, Wen, X. [US/US]; 1145 Wellington Drive, Victor, NY 14564 (US). RICHARDSON, Gary, A. [US/US]; 170 Goldenrod Lane, Rochester, NY 14623 (US). EGAN, Robert, J. [US/US]; 6744 Route 20A, Livonia, NY 14487 (US). SPOOR, Ronald, D. [US/US]; 3343 Country House Road, Penn Yan, NY 14527 (US). HOVEY, Larry, C. [US/US]; 918 Willits Road, Ontario, NY 14519 (US).

(74) Agents: POWERS, Jeffrey, B. et al.; Bausch & Lomb Incorporated, One Bausch & Lomb Place, Rochester, NY 14604-2701 (US).

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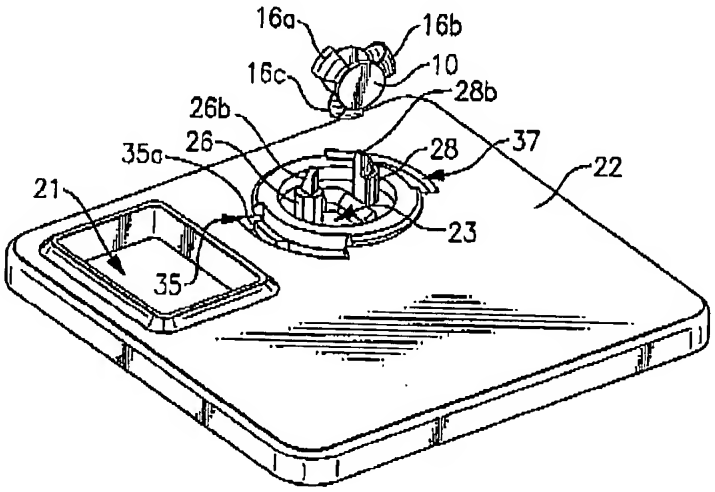
(54) Title: HOLDER FOR DUAL OPTIC IOL



(57) Abstract: The present invention provides a holder/package for supporting a two optic accommodating intraocular lens device. The holder/package is capable of holding the device, for example while taking measurements or performing manufacturing process steps on the device and/or for packaging and shipping of the device. In a preferred embodiment, the holder/package supports the device along first and second haptics thereof with the optics substantially untouched by the holder/package.

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HOLDER FOR DUAL OPTIC IOL

Background of the Invention

The present invention relates to devices and methods for holding and/or packaging optical lenses such as intraocular lenses. More particularly, the present invention relates to a holder and/or packaging device and method for safely supporting an accommodating intraocular lens device having at least two optics interconnected by one or more haptics.

Intraocular lenses having a single optic have been known and used for many years. More recently, accommodating intraocular lens devices having two optics interconnected by one or more haptics have been disclosed in the following U.S. patents and applications to Faezeh Sarfarazi, the entirety of which are incorporated herein by reference:

US 5,275,623 "Elliptical Accommodative Intraocular Lens For Small Incision Surgery";
US 6,423,094 "Accommodative Lens Formed From Sheet Material";.
US 6,488,708 "Open Chamber Elliptical Accommodative Intraocular Lens System";
USSN 10/445,762 filed on 5/27/03 entitled "Mold for Intraocular Lens".

The Sarfarazi accommodating lens device includes two optics, one negative and the other positive for placing in the evacuated lens capsule of an eye. The optics are interconnected along their peripheries by one or more haptics which space the optics from each other and assist in properly positioning the device in the eye. The haptics are formed from a flexible material such that they may flex in response to forces exerted by the eye's ciliary muscles which control accommodation. The haptics will thus flex and bow further radially outwardly upon a compressive force being applied to the device, whereby the two optics are drawn closer together to achieve an accommodative effect in the eye. When the ciliary muscles relax, the haptics flex in the opposite direction (toward a straightened positioned) causing the optics to space further apart and the lens device returns the eye to its natural, unaccommodative state.

As stated above, single optic intraocular lenses have been known and used for decades while the two lens accommodative intraocular lens device is new and not yet

seen on the market. It will be appreciated that manufacturing, packaging and otherwise handling a two optic lens device presents issues not present in the manufacture, packaging and handling of single optic intraocular lenses. For example, during design and manufacture of intraocular lenses, certain measurements and processes may be performed on the device to ensure the device achieves its design parameters. Typically such measurements and processes require the two optics of the device be held in their normally spaced apart condition since contacting of the optical surfaces with each other or with parts of the holder could damage the delicate lenses. Likewise, packaging of a two optic IOL requires the two optics of the lens remain in their normally spaced apart condition and free from contact with any part of the package which could otherwise occur due to vibration and forces during transportation and handling.

Summary of the Invention

The present invention provides a holder and/or package for safely supporting a two optic accommodating intraocular lens device. In a preferred embodiment, the holder acts as the package for storage and shipment of the IOL device to a surgeon. The holder/package includes a base with spaced support posts extending substantially perpendicularly therefrom which removably support the haptics of the IOL device. The posterior optic and anterior optic extend freely therefrom in their normally spaced condition and substantially untouched by the holder. In an advantageous embodiment, the holder acts as the package for storing and shipping the IOL device to a surgeon while maintaining the optics in their spaced condition.

Brief Description of the Drawing

Figure 1A is a perspective view of an embodiment of an accommodative intraocular lens which may be supported by the holder of the present invention;

Figure 2 is a perspective view of an embodiment of the inventive holder;

Figure 3 is a side elevational view of the holder of Fig. 2 showing the lens of Fig. 1 and the cover in spaced relation to the holder base;

Figure 4 is a perspective view of the holder base showing the lens of Fig. 1 spaced above the support posts thereof;

Figure 5 is a perspective view the holder base showing the lens of Fig. 1 mounted to the support posts thereof;

Figure 6 is a side elevational view of Fig. 5;

Figure 7 is a perspective view showing the bottom of the holder base;

Figure 8a is a perspective view of an alternate embodiment of the holder base;

Figure 8b is a cross-sectional view taken generally through the line 8b-8b of Figure 8a;

Figure 9 is a further alternate embodiment of the holder base; and

Figure 10 is a further alternate embodiment of the holder base and cap.

Detailed Description

Referring now to the drawing, there is seen in Fig. 1 a representative embodiment of an accommodative intraocular device 10 which may be used with the present invention. Briefly, lens device 10 includes first and second optics 12, 14 interconnected by one or more, but preferably three haptics 16a, 16b and 16c defining three open spaces 18a, 18b, 18c therebetween, respectively. Haptics 16a-c bow outwardly past the optic perimeters 12p, 14p and are flexible whereby the optics may move alternately toward and away from each other generally along the optical axis x-x. Optics 12, 14 are preferably flexible and may be made of any suitable IOL lens material such as silicone, for example. It is understood that the present invention is a holder/package for a lens device and therefore the particular optic and haptic configurations of a lens device which may be supported by the inventive holder/package may vary from the exemplary lens shown and described herein.

Referring to Figs. 2-7, a preferred embodiment of the holder/package is indicated generally by reference numeral 20. Holder/package 20 includes a base 22 and a removable cover 24 which may be made of any desired material such as plastic. If the holder/package is to be used to sterilize the lens 10 held thereby, holder/package 20 needs to be made of a material that can withstand the sterilization method employed. For example, when using ETO sterilization, a plastic such as PVC may be used.

In the preferred embodiment, holder/package base 22 includes first and second lens supports 26, 28 extending substantially perpendicularly to base 22. Supports 26, 28 are spaced apart a distance sufficient to enable the mounting of lens 10 thereto in the manner described below. Supports 26, 28 may have a variety of configurations but in

their preferred form include bottom and top segments 26a, 26b and 28a, 26b, respectively where top segments 26b, 28b are configured with a smaller diameter than their respective bottom segments such that a shoulder 26c, 28c is formed at the juncture of the top and bottom segments. Shoulders 26c, 28c form a ledge upon which the downwardly facing edges of haptics 16a and 16b may rest when lens 10 is mounted to supports 26, 28. To mount the lens 10 to holder/package 20, lens 10 is initially positioned above supports 26, 28 as seen in Figs. 3 and 4 with one haptic 16c facing downwardly between supports 26, 28 and haptics 16a, 16b aligned above supports 26, 28, respectively. Lens 10 is then lowered toward base 22 with haptics 16a, 16b passing outwardly and over support top segments 26b, 28b until the downward facing edges 16a', 16b' thereof come to rest on shoulders 26c, 28c, respectively. This fully mounted position of lens 10 on supports 26, 28 is seen in Figs. 5 and 6. In this position, lower-most haptic 16c is located between and untouched by supports 26, 28. It is furthermore preferable that this haptic not contact base 22 which may include an opening 23 between supports 26, 28 wherethrough haptic 16c may at least partially extend and freely move without touching the perimeter of the opening due to the sizing and chamfered sides thereof (see Figs. 4-7). Opening 23 may also assist in passage of sterilizing media (e.g., steam) to lens 10.

Although two haptics 16a, 16b are shown and described herein as locating over supports 26, 28, it is noted that the two haptics may be formed as a single haptic which engages the supports 26, 28. As stated previously, the invention is not limited to the lens design shown herein and may include one or more haptics of various configurations as desired. In this respect, it is noted that the support top segments 26b, 28b in particular may have any desired shape and cross-section to more closely conform to the shape of the haptic(s) being located thereon.

With lens 10 mounted to supports 26, 28 as described above, optics 12, 14 remain in their normally spaced position and substantially untouched by holder/package 12. As seen best in Fig. 6, support top segments 26b, 28b may be shaped to more closely conform to the shape of the facing surfaces of the haptics 16a, 16b mounted thereon. More particularly, the outwardly facing surfaces 26b', 28b' of top segments 26b, 26b may be curved to follow the curvature of the inwardly facing surfaces 16a', 16b' of haptics 16a, 16b, respectively (see also Fig. 1). As mentioned above, the spacing of

supports 26, 28 enable lens 10 to be mounted thereon substantially as shown and described herein. In this regard, it is noted that haptics 16a, 16b are preferably in close but not overly tight engagement with support top segments 26b, 28b. As such, lens 10 remains in its normally relaxed condition with optics 12, 14 spaced and lying substantially perpendicular to base 22. Optics 12, 14 and haptics 16a-c are preferably substantially unstressed when mounted to supports 26, 28.

Once lens 10 is mounted to supports 26, 28, cover 24 may be removably secured to base 22 over lens 10 and supports 26, 28 as seen in Figs. 2 and 3. Cover 24 protects lens 10 and preferably does not come into substantial contact therewith. The top portion 25 is attached to a skirt 27 forming a space 29 wherein lens 10 and supports 26, 28 reside when cover 24 is attached to base 22. The space 29 is large enough to accommodate lens 10 and supports 26, 28 therein, yet small enough to prevent lens 10 from inadvertently decoupling from supports 26, 28 during handling or shipping. In this regard, when cover 24 is coupled to base 22, the inside surface of top portion 25 lies in close proximity to upper-most parts 16a'', 16b'' of haptics 16a, 16b (Fig. 6), thereby acting as a stop against which haptic parts 16a'', 16b'' will abut should they be urged in a direction off of supports 26a, 28b.

In its preferred form, cover top portion 25 is round and skirt 27 is cylindrical although other configurations are possible. One or more openings 29a-c may be provided in top portion 25 and/or skirt 27 for passage of sterilizing media therethrough. Releasable coupling means are provided which may be in the form of first and second finger portions 31, 33 extending downwardly from the free edge of skirt 27 which cooperate with slots 35, 37 formed in base 22 radially outwardly of supports 26, 28, respectively. As seen best in Fig. 7, the free ends 31a, 33a of finger portions 31, 33 extend through slots 35, 37 upon initial attaching of cover 24 to base 22. Cover 24 is then rotated until the finger free ends 31a, 33a engage with the slot shoulders 35a, 37a (Fig. 5) in the manner of a bayonet type coupling. To remove cover 24, the cover 24 is simply rotated in the opposite direction until the fingers disengage from the slot shoulders at which time cover 24 may be raised relative to base 22. Of course other types of removable coupling means may be employed.

A depression 21 or the like may be formed in base 22 to provide a space in which lens 12 may be inspected and handled (e.g., with tweezers) once removed from supports 26, 28.

Figures 8a and 8b show an alternate embodiment of a base 122 having first and second spaced supports 126, 128 extending substantially perpendicularly from a base 122. Base 122 includes a central circular portion 122a surrounded by a circular wall portion 122b. Supports 126, 128 are spaced from wall portion 122b forming a space 123, 125 therebetween. Lens device 10 is mounted to base 122 by passing haptics 16a, 16b over and about supports 126, 128 with the haptics 16a, 16b coming to rest in spaces 123, 125, respectively, and optics 12, 14 lying in their relaxed, spaced condition. As seen best in Fig. 8b, the top extents of the outwardly facing surfaces of haptics 16a, 16b gently abut wall portion 122b with the bottom extents thereof gently abutting supports 126, 128, respectively, thereby preventing lateral movement of lens device 10 along an axis intersecting supports 126, 128. Base 122 thus supports lens device 10 by capturing the haptics between the supports and wall portion with the optics 12, 14 lying spaced and substantially perpendicular to base central circular portion 122a. Central circular portion 122a may include a through hole 122c to allow passage of sterilizing media therethrough.

Figure 9 shows yet another alternate embodiment of a base 222 having a unitary support 226 of generally planar configuration extending substantially perpendicular to central base portion 222a. Opposite side edges 226a, 226b are spaced inwardly of wall portion 222b which encircles central portion 222a. Support 226 may include a central opening 226c to provide clearance between the support 226 and optics 12, 14 of the lens device 10. Lens device 10 is mounted thereto by passing haptics 16a, 16b over and about opposite side edges 226a, 226b with the lower-most edges of haptics 16a, 16b coming to rest at the juncture of side edges 226a, 226b and circular base portion 222a, respectively. It is noted that while support 126 is a unitary structure, the opposite side edges 226a, 226b thereof may be considered as first and second supports, respectively, as those terms are used elsewhere herein. The support top edge 226d may be convexly curved to generally follow the inside contour of haptic 16c resting thereon. When lens device 10 is mounted to support 226, optics 12, 14 lie spaced and substantially perpendicular to base portion 222a.

Figure 10 is yet a further alternate embodiment of a base 322 having first and second supports 326, 328 over which haptics 16a, 16b may extend in a manner similar to the embodiments of Figures 2-9. One or more posts 330a-d extend substantially perpendicularly from base 322 on either side of and spaced radially outwardly of supports 326, 328. Posts 330a-d act to further guide and control the lateral movement of haptics 16a, 16b extending therebetween. An alternate configuration of cap 324 is also shown.

Although the invention has been described with reference to several embodiments, it is understood that further variations may be made without departing from the full scope of the invention as defined by the claims which follow.

What Is Claimed Is:

1. A holder/package for an intraocular lens device having first and second optics interconnected by one or more haptics, said holder/package comprising:

a) a base;

b) first and second supports attached to said base;

whereby said intraocular lens device may be removably mounted to said holder/package by engaging said one or more haptics with said first and second supports, respectively, with said first and second optics lying spaced from each other and substantially perpendicular to said base.

2. The holder/package of claim 1 wherein first and second haptics interconnect said first and second optics, and wherein said first and second haptics engage said first and second supports, respectively.

3. The holder/package of claim 2 wherein said supports are separated a distance permitting said intraocular lens device to be engaged therewith in a substantially unstressed condition.

4. The holder/package of claim 1 and further comprising a removable cover for attaching to said base in covering relation to said supports and said intraocular lens device.

5. The holder/package of claim 4 wherein said cover, when attached to said base, acts as a stop to prevent said intraocular lens from releasing from said supports.

6. The holder/package of claim 4 wherein said cover and base are attached to each other with a bayonette-type coupling.

7. The holder/package of claim 1 wherein said first and second supports each include a lower and upper segment having a shoulder formed at the juncture of the lower and upper segment.

8. The holder/package of claim 5 wherein said one or more haptics extend around said supports and rest on said shoulders when said intraocular lens device is mounted to said supports, respectively.

9. A method for holding an intraocular lens device having first and second optics interconnected by one or more haptics, said method comprising the steps of:

a) providing a base;

b) providing first and second supports attached to said base;

c) removably mounting said one or more haptics of said intraocular lens device to said first and second supports, respectively, whereby said first and second optics are spaced from each other.

10. The method of claim 9 wherein first and second haptics are removably mounted to said first and second supports, respectively.

11. The method of claim 10 wherein a third haptic extends between said first and second supports when said intraocular lens device is mounted to said first and second supports, respectively.

12. The method of claim 9 and further comprising the step of providing a cover for removable attachment to said base in covering relation to said support and said intraocular device.

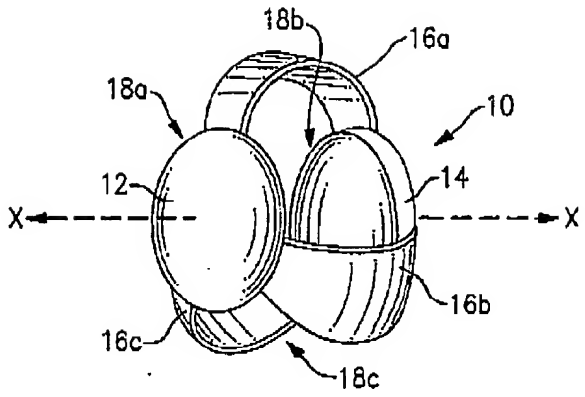


FIG.1

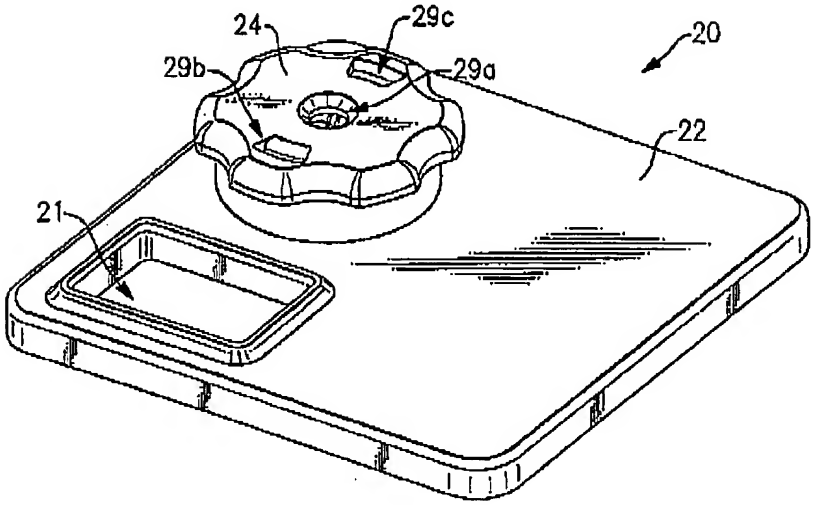


FIG.2

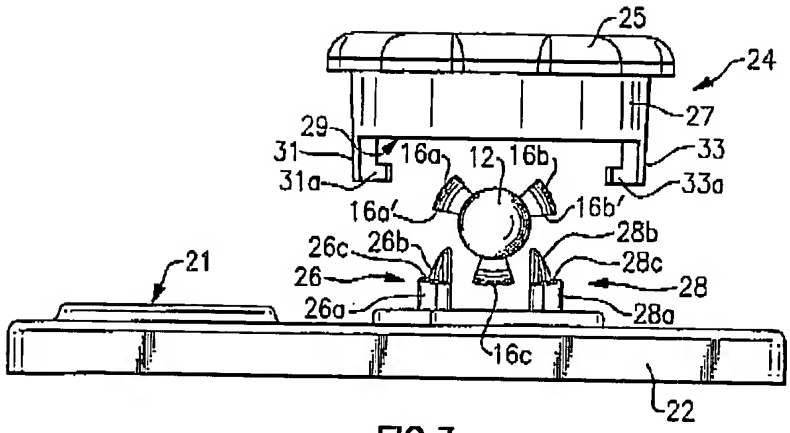

25
24
27
29
31
31a
16a
12
16b
33
33a
16a'
16b'
28b
26c
26b
28c
21
26
28
26a
28a
16c
22

FIG.3

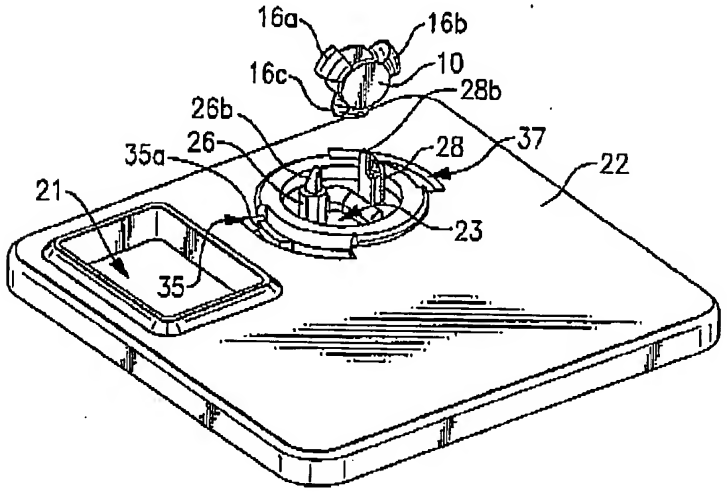
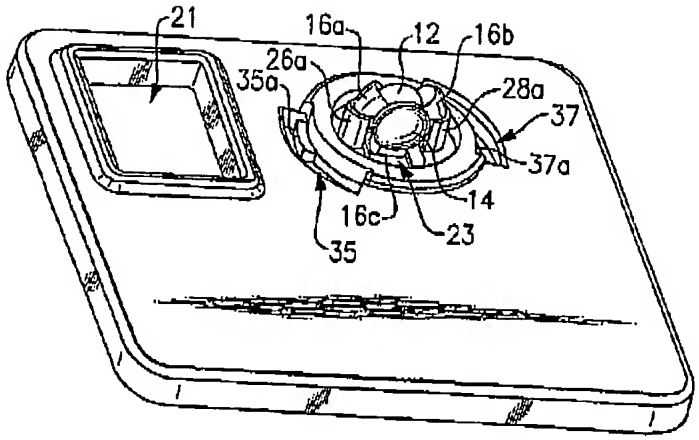

16a
16b
16c
10
28b
26b
26
28
37
35a
22
21
23
35

FIG.4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16a
12
16b
26a
35a
28a
37
37a
14
16c
23
35

FIG.5

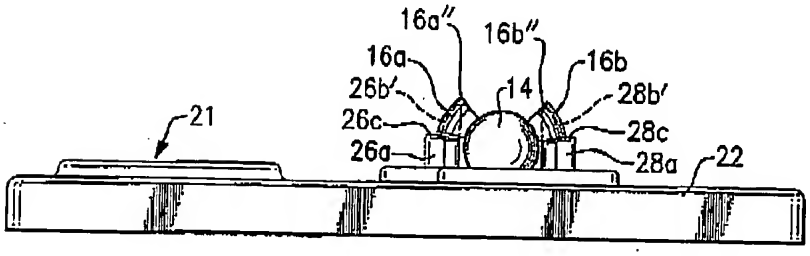
16a''
16b''
16a
16b
26b'
14
28b'
21
26c
28c
26a
28a
22

FIG.6

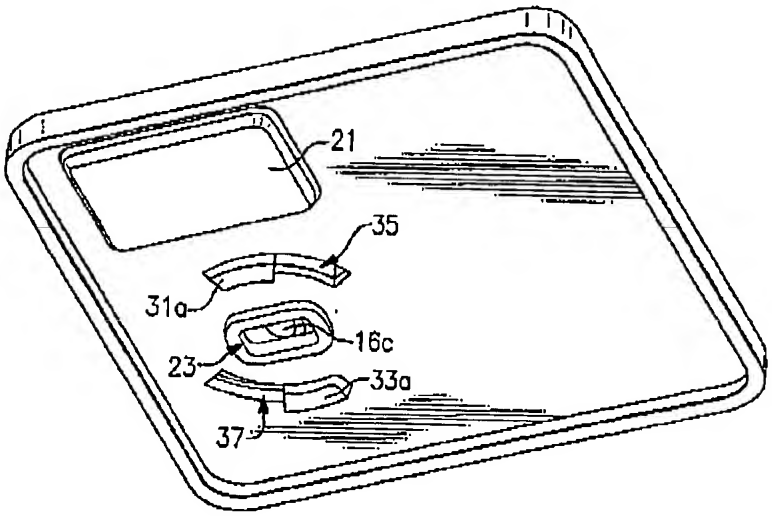
21
35
31a
16c
23
33a
37

FIG.7

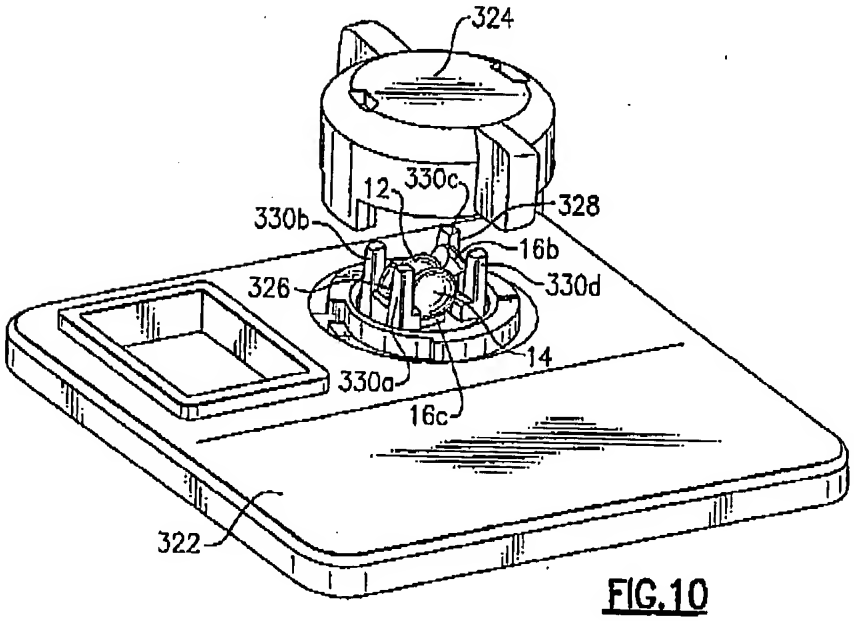
324
12
330c
328
330b
16b
326
330d
14
330a
16c
322

FIG.10

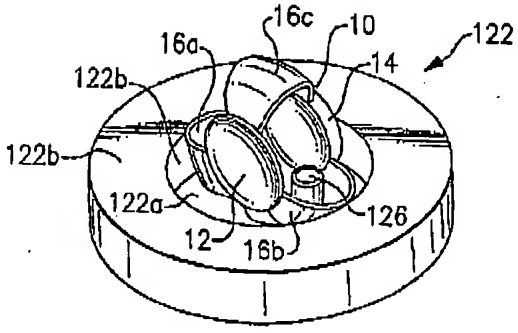

FIG.8a

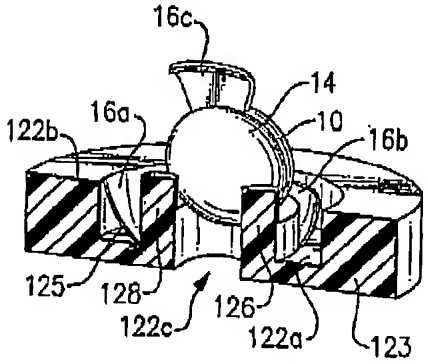

FIG.8b

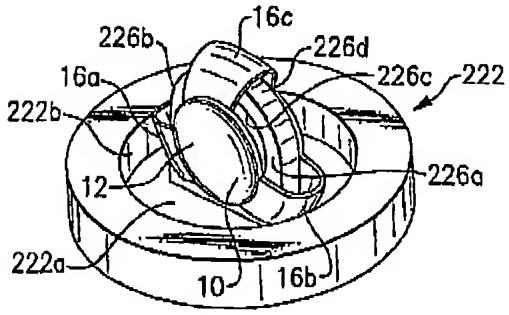

FIG.9